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Urology

Night-time voids, level of bother and sleep characteristics in a non-patient population of wearable devices users

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Abstract

Introduction: Nocturia is a highly prevalent and bothersome medical condition characterised mainly by the need to wake up to pass urine during the main sleep period. Using data from wearable devices, it is possible to examine the sleep of large cohorts in natural settings. This study seeks to use data from connected smartwatches combined with a one-time survey to explore the presence of nocturia and associated level of bother and sleep characteristics in a non-patient cohort of wearable device users representing a broad age range.

Methods: The data used come from a retrospective dataset containing sleep data from Withings watches of 250 000 users and a prospective dataset containing answers to a 10-item questionnaire completed by a subset of users in the retrospective dataset. **Results:** The prospective dataset contained 6230 users. Overall, 6.0%, 15.3% and 38.9% of users in the age groups 18-44 years, 45-64 years and 65-90 years, respectively, reported 2 or more nocturnal voids as their customary voiding pattern, corresponding to levels of nocturia consistent with previous literature. The level of bother associated with nocturia was higher among younger users with 27.8% of users aged 18-44 years reporting that their daytime activity was highly affected versus just 14.1% among those aged 65-90 years. A higher number of reported voids per night was associated with watch-derived measures of a lower sleep efficiency, a longer awake duration at night and a shorter first uninterrupted sleep period.

Conclusion: This study suggests not only that nocturia is present among the younger population but also that the younger are more bothered by this medical condition. Using data from wearables it was possible to establish that there is an association between the number of nocturnal voids and sleep characteristics.

1 | INTRODUCTION

Nocturia is a highly prevalent and bothersome medical condition characterised by the need to wake up to pass urine during the main sleep period, with each urination followed by sleep or the intention to sleep, as per the International Continence Society (ICS) 2018 definition.¹ Awakening 2 or more times per night to void is considered a clinically relevant threshold according to the International Consultation on Incontinence Research Society 2018 definition.²

It is well-established that nocturia has wide-ranging implications for quality of life (QoL) as well as quality of sleep, and even mortality, mainly through persistent, repeated sleep interruptions.³⁻⁸

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Compared with other common causes of sleep disturbance in older adults (eg, physical pain, heartburn, etc), nocturia is the most common cause of sleep disruption.⁹ Most nocturia research has focused on clinic-based patients and by nature of traditional research methods studied a limited number of participants. Research methods using data from wearable devices may allow to study larger groups of subjects, including people who are not usually patients visiting a physician.

Wearable devices are capable of continuously capturing individual health-related data and have been in use since the early 1960s in clinical setting, when the Holter monitor was released. Today wearable medical devices have multiple uses supporting telemedicine and facilitating remote health monitoring of patients. The data can be sent from the wearable to the physician's office, avoiding the need for office visits, ultimately making possible preventive medicine and improving quality of care.

However, there is another segment which is rapidly gaining popularity, represented by consumer health-oriented devices. In 2007 Fitbit[®] introduced first health monitoring to consumers.¹⁰ These are not approved as medical devices, however, are used by large segments of population and are capable to collect, store, analyse and interpret a large amount of data, which would not be possible through traditional epidemiology studies. In 2013, 69% of US adults reported tracking one or more health indicators, such as weight or exercise, and 21% of those used technology, such as an app or device.¹¹ In a recently published review Hicks and colleagues concluded that analysing the data generated by commercial wearables and apps has the potential to alter how we study human behaviour and how we intervene to improve health.¹² Smartphone-generated datasets have recently been used to evaluate the relationship between physical activity and geographic location, age, gender, etc Research using wearables is used for advancing knowledge on disease states including cardiovascular medical conditions, Parkinson's disease and multiple sclerosis.¹³⁻¹⁵

This study reports on analyses of data collected routinely by Withings wearables as well as data from a prospective survey disseminated to members of the Withings Community to:

- 1. Explore and qualify the utility of wearables data for nocturia research.
- Characterise sleep patterns and interruptions with particular focus on a young, working-age, non-patient population, segmented by gender and age group.
- Assess the association by age group between night-time voids and level of bother at night and effect on daytime activities.
- 4. Assess the association between night-time voids and sleep characteristics (sleep duration, awake duration at night, sleep efficiency (SE) and first uninterrupted sleep period [FUSP]). FUSP is defined as the period from time asleep to time of first awakening.

We are using the term "User-Reported-Outcomes" replacing the established terminology "Patient-Reported-Outcomes" as the data collected are not coming from known patients, but rather from presumably healthy subjects, users of wearable devices.

What's known?

• It is well established that the incidence of nocturia increases with age and that nocturia is associated with a lower sleep quality and quality of life.

What's new?

- This study demonstrated the feasibility of using data from wearables to study the association between nocturia and sleep.
- We learn that nocturia does not affect elderly people only, but is also present in a young, working-age population.
- Moreover, the younger population reports a higher level of bother from nocturia at night and effect on daytime activity than the elderly people, with sleep disturbance strongly correlated with the number of nocturnal voids.

2 | METHODS

The datasets used in this study were as follows:

- A retrospective dataset collected from a cohort of 250 000 Withings users routinely tracking their sleep.
- A prospective dataset containing answers to a one-time 10-item questionnaire (see Appendix A) sent out electronically to 138 674 of the 250 000 users of the retrospective dataset. For the current analysis, we confined our analyses to only five of these items: Q2, Q3, Q6 and Q9 dealing with issues related to nocturia, and Q4 related to sleep. Analyses of other items will be reported separately.

The Withings Community cited here is represented by users of three types of Withings Watches: Steel HR watch (firmware 3351) (50%), Steel watch (firmware 1690) (45%) and Pulse Ox tracker (firmware 1761) (5%). The total sleep duration (TSD) measured by the Withings watches was previously validated.^{16,17} Withings users have bought their Withings devices on their own account completely independently of this study.

The informed consent process required two steps:

- Each member of the Withings Community had previously consented during registration to have their data used for research purposes and to be contacted, eg, for surveys.¹⁸ The survey used in this study was introduced to potential responders within the Community through the Withings Health Mate App.
- Once respondents confirmed their interest to participate in the survey, by accessing the survey introduction page, a project-specific Consent Form was presented; those who consented were permitted to access the survey page.

Data collection followed the European Pharmaceutical Market Research Association 2017 code of conduct for international healthcare market research,¹⁹ the ESOMAR GRBN Guidelines on Mobile Research,²⁰ the US Office for Human Research Protections (OHRP) regulations—category 2 exemption²¹ and the GDPR Regulations.²² The project was conducted in a virtual environment where there are no physical research sites and data were collected either retrospectively or prospectively through an observational survey, from non-patient users with no direct contact. Ethical approval is not required for surveys of this nature, as the purpose of the research is to improve understanding and not test any interventions or treatments. The study was designed, and the research was sponsored by the Department of Global Medical Affairs, Ferring Pharmaceuticals, St-Prex, Switzerland.

The gender, birthdate and country of origin were self-identified information provided by users when signing up as a Withings user and obtained in this study from the Withings database.

The project had two phases: a retrospective collection followed by a prospective survey. Retrospective wearable data included all available Withings wristwatch sleep data for the cohort of 250 000 users over 1 year, from 01 November 2017 to 31 October 2018 and for the respondents to the questionnaire from 01 January 2018 to 01 January 2019. Sleep data are collected automatically by the Withings watches when worn while sleeping. The Withings watch is equipped with sensors capable of determining whenever the watch is not worn on the wrist. Sleep is detected by the watch via a proprietary algorithm based on sequential time intervals without detectable movement.

The sleep variables collected and used in this study were (a) TSD; (b) nocturnal time awake; (c) into bed time (IBT) and (d) out of bed time (OBT).

Sleep efficiency was calculated as TSD/Time between IBT and OBT. When extracting the data from the Withings database, sleep data were included only if categorised as 'nights' by Withings (ie, no naps) and an upper limit on TSD was set at 20 hours.

In addition to the above sleep variables, the FUSP was calculated and extracted in December 2019 from minute-by-minute Withings sleep data and determined as the time span between the first minute asleep and the first minute awake during the night.

Validated nocturia QoL questionnaires exist.²³⁻²⁵ However, in the context of a questionnaire disseminated in a mobile application, it was desirable to present the users with a short survey that evaluated not only QoL but also other aspects of their sleep. Hence, the assessment of QoL was reduced to just two questions (Question 6 "How bothered are you by having to get up to void each night, and thus having a disrupted sleep?" and Question 9 "How much does bothersome nighttime urination affect your daytime activities (work, driving, other activities)").

Questionnaire responses were collected prospectively between 15 December 2018 and 15 January 2019. Only respondents with complete questionnaire answers who met the defined criteria listed below were retained:

- 1. Respondents had to be 18 years or above to respect ethical guidelines on informed consent.
- 2. Respondents needed at least 5 nights of sleep data measured by the wristwatch.
- Respondents who answered a lower value on number of wakeups (Question 2) than on number of voids (Question 3) were excluded.
- 4. Incompatible and/or equivocal free field answers on questionnaire items Q4, Q5 and Q8 also resulted in exclusion (eg, "0h5" might refer to 5 minutes, 0.5 hours or 50 minutes), although some of those items were not analysed in this study.

2.1 | Statistical analyses

We relied upon simple descriptive statistics (mean, standard deviation) to examine variables with continuous distributions. Associations between categorical variables were analysed using Chi-squares. We examined relationships between categorical variables and continuous dependent variables using one-way analyses of variance (ANOVA).

Data were analysed in Python using pandas library and the scipy stats module.

3 | RESULTS

The results communicated here are focused on the association between the extent of nocturia, level of bother and sleep interruptions. Data used are sourced from the User-Reported Outcomes in the prospective cohort of survey respondents and also includes selected wearable-derived sleep characteristics from the retrospective study.

3.1 | Retrospective dataset

The cohort of the retrospective study included 250 000 users (see Table 1). The distribution of users is shown by country in Appendix B.

The TSD of users from the retrospective data was 443 minutes (SD 50.4). As shown in Figure 1A,B, the sleep duration and the SE decreased with age, a trend previously reported.²⁶ The TSD levels of the elderly people are very similar to levels previously reported.²⁷

TABLE 1	Number of users by gender in the retrospective
dataset	

	Number of users (%)
All	250 000 (100)
Male	142 451 (57.0)
Female	107 549 (43.0)

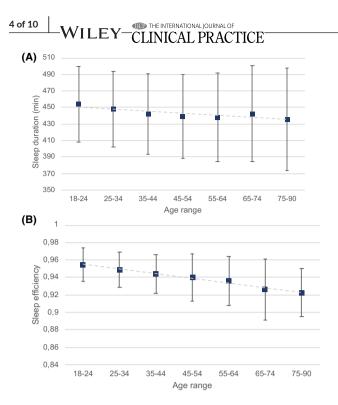


FIGURE 1 Mean and standard deviation (A) sleep duration detected by Withings watch of users in the retrospective dataset by age group (statistically significant effect of age: F = 7.0, P < .0001) and (B) sleep efficiency in the retrospective dataset by age group (statistically significant effect of age: F = 27.5, P < .0001)

3.2 | Prospective dataset

For the prospective dataset, 138 674 users were offered the opportunity to complete the survey, and 7141 individuals did so, which represents a 5.15% response rate. After applying the quality exclusion criteria listed above, 6230 (87.2%) subjects were included in the analysis. The FUSP was not available for 24 users having deleted their Withings accounts between January and December 2019. The mean age of the 6230 respondents was 47.4 years (SD = 13.9; range 18-90) and overall 59.5% of the respondents were men. The proportion of women who responded to the questionnaire was lower in the age groups of 35 years old and above compared with the younger age groups. The number of respondents split by age and gender can be seen in Figure 2 and their geographic distribution is shown in Appendix C.

3.3 | Voiding frequency

The self-reported number of voids per night was obtained through the answer to Question 3 of the questionnaire "How often do you usually get up during the night to urinate?". A frequency of two or more voids is generally considered to be clinically significant and bothersome nocturia.^{2,28,29} Of all respondents, 14.2% indicated getting up to urinate "2 times" or "3 or more times" per night. The percentage of respondents indicating 2 or more voids increased with age, from 4.1% in the 18- to 24-year-old group to 49.1% in the 75- to 90-year-old group.

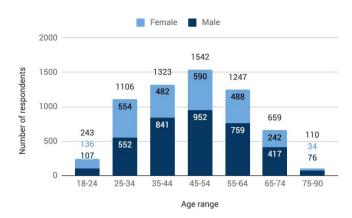


FIGURE 2 Number of respondents split by age and gender

The proportion of respondents within each age and gender group who indicated 2 or more voids is shown in Figure 3. It can be seen that among women, the percentage of respondents with nocturia was higher in the younger age groups below 65, whereas in the older age groups (65 years and above), men were more affected by nocturia than women.

Of the respondents who answered 3 or more awakenings per night (Question 2), 16.6% reported 3 or more voids per night, 21.0% reported 2 or more voids per night and 62.4% reported 0-1 void per night. Of respondents who answered 2 awakenings per night, 23.0% reported 2 voids per night and 77.0% reported 0-1 void per night.

3.4 | Voiding frequency and bother by age

As expected, the proportion of respondents who answered that they were "quite a bit" or "extremely" bothered by having to wake up to void (Question 6 "How bothered are you by having to get up to void each night, and thus having a disrupted sleep?") increased with the number of voids: 55.3% for respondents with 3 or more voids versus 37.4% and 23.2% for those with 2 and 0-1 voids, respectively (see Figure 4). Similarly, a higher proportion of participants with 3 or more voids indicated that their daytime activities (Question 9 "How much does bothersome night-time urination affect your daytime activities (work, driving, other activities)") were "quite a bit" or "extremely" affected by night-time voids compared with those with 2 or 0-1 voids: 20.1% vs 11.0% and 3.3%, respectively (see Figure 5). The associations between number of voids and night-time and daytime bother were statistically significant, as demonstrated in chi-square analyses (see Appendix D).

Interestingly, a higher proportion of the younger are bothered by nocturnal voids. Among those aged 18-44 years and those aged 45-64 years 55.6% and 62.7%, respectively, reported a high level of bother at night (Question 6) at 3 or more voids per night versus 47.4% of those 65-90 years old (see Figure 4). Similarly, for daytime bother (Question 9) at 3 or more voids per night, 27.8% among those aged 18-44 years reported their daytime activity being "Quite a bit" or "Extremely" affected compared with 14.1%

CLINICAL PRACTICE All Male Female FIGURE 3 Proportion of respondents 60.0% 55.3% by age and gender who answered "2 49.1 times" or "3 or more times" to Question 3 39.6% Share of respondents "How often do you usually get up during 40.0% the night to urinate?" 20.8% 22.5% 19.6% 20.0% 11.7% 10.9% 1 7.0% 8.5% 7.0% 6.6% 5.2% 41% 6.1% 3.3% 0.9% 0.0% 18-24 35-44 25-34 45-54 55-64 65-74 75-90 Age ΔII = 18-44 = 45-64 65-90 (A) ₆₀ 80.0%

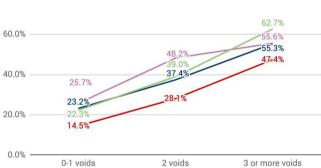


FIGURE 4 Proportion of respondents (y-axis) indicating "Quite a bit" or "Extremely" on Question 6 "How bothered are you by having to get up to void each night, and thus having a disrupted sleep?" by age and number of voids (x-axis), ie, answers to Question 3 "How often do you usually get up during the night to urinate?"

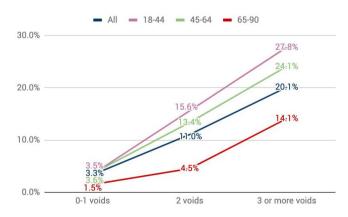
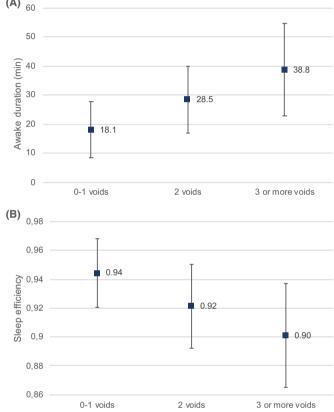


FIGURE 5 Proportion of respondents (y-axis) indicating "Quite a bit" or "Extremely" on Question 9 "How much does bothersome nighttime urination affect your daytime activities (work, driving, other activities)" by age and number of voids (x-axis), ie, answers to Question 3 "How often do you usually get up during the night to urinate?"

of those aged 65-90 years (see Figure 5). These were statistically significant age effects as confirmed by chi-square analyses (see Appendix E).



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FIGURE 6 Mean and standard deviation (A) awake duration at night derived from Withings watches in minutes by number of voids, ie, answers to Question 3 "How often do you usually get up during the night to urinate?" and (B) sleep efficiency derived from Withings watches by number of voids, ie, answers to Question 3 "How often do you usually get up during the night to urinate?"

3.5 | Association between voiding frequency and sleep characteristics as recorded with Withings watches

Time awake was 38.8 minutes among respondents with 3 or more voids vs 18.1 minutes among those with 0-1 voids (see Figure 6A). The difference across all three groups was significant by one-way ANOVA (F = 656, P < .0001).



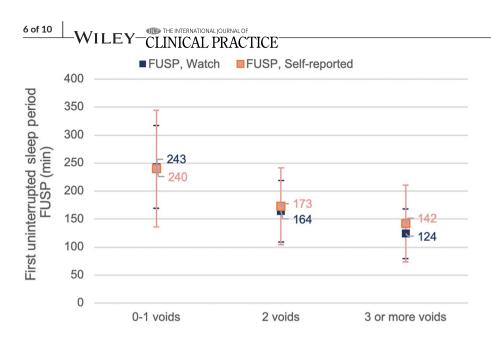


FIGURE 7 Mean and standard deviation first uninterrupted sleep period (FUSP) derived from Withings watches and self-reported (Q4) by number of voids, ie, answers to Question 3 "How often do you usually get up during the night to urinate?"

Similarly, the group with 3 or more voids had a mean SE of 0.90 versus 0.94 for those with 0-1 voids (see Figure 6B). The differences across all three groups in SE was also statistically significant by one-way ANOVA (F = 2383, P < .0001).

3.6 | FUSP: user-reported outcomes and Withings watches-derived results

The FUSP derived from the Withings watches was 243 minutes among those with 0-1 voids vs 124 minutes among those with 3 or more voids. The self-reported FUSP was obtained through the answer to Question 4 of the questionnaire "What is the length of the first period of uninterrupted sleep you usually get at night (DO NOT include time that you spend getting to sleep at night)?"). The self-reported FUSP was 240 minutes among those with 0-1 voids vs 142 minutes among those with 3 or more voids (see Figure 7). The differences across all three groups in FUSP derived from the Withings watches and self-reported was statistically significant by one-way ANOVA (F = 581, P < .0001 and F = 215, P < .0001, respectively).

4 | DISCUSSION

To our knowledge this is the first study exploring and describing the point prevalence of nocturia in a non-patient population using data collected directly by wearable devices and from User-Reported Outcomes gathered through software associated with the wearables. Considering the large number of participants and the large dataset evaluated, this study suggests that members of a healthminded "wearable community" are responsive and interested in contributing to populational health research and that using this channel could be a rapid and cost-effective way of engaging and gathering insights.

The results presented here show that sleep data from wearable devices are aligned with published data on sleep obtained through

established methods of measurement, indicating that using wearables is appropriate for nocturia and sleep research in large populations.²⁶ The User-Reported Outcomes of the frequency of voiding showed that the proportion of users reporting 2 or more voids increases with age, reaching 6.0%, 15.3% and 38.9% in the age groups 18-44 years, 45-65 years and 65-90 years, respectively. These figures correspond to previously reported levels.^{30,31} The User-Reported Outcomes also indicated that in the younger population below 65 years old, women reported 2 or more voids more frequently than men (11.9% vs 9.9%), whereas in users 65-90 years old, more men than women reported 2 or more voids (42.0% vs 33.3%). The results of the FUSP data analysis are of practical interest because of strong alignment of the values reported by users and the ones measured independently by the watch, suggesting that clinicians could consider wearable-derived sleep reports as a useful tool to evaluate the impact of nocturia or other conditions (eg, obstructive sleep apnoea) on sleep, in absence of access to polysomnography.

While analyses showed an association between nocturia and sleep parameters, the method used to prospectively collect data on night-time voids and subjective sleep quality, ie, the 10-item questionnaire, does not allow detailed ascertainment of the potentially multiple underlying causes of the nocturia, eg, nocturnal polyuria, users' lifestyle (eg, drinking habits), concomitant medications (eg, diuretics) or medical comorbidities (eg, diabetes, congestive heart failure). Although the study focuses on working-age population, another limitation is the smaller proportion of users of 65 years of age and above (12.3%), an age group that has been well studied for nocturia in clinical trials, where patients 65 years or older constitute approximately 50% of all patients enrolled.^{32,33} With time and the continuing use of wearables in the current younger population, this age group should be better represented in such research in the future.

Typically, patients with nocturia are evaluated with a thorough history and physical examination focusing on their complaints including sleep quality, level of bother and any clinical condition or comorbidity, which could cause storage dysfunctions or an increased urine output during the night (nocturnal polyuria–NP).³⁴ Being a complex medical condition, nocturia is difficult to diagnose and consequently to manage. It also requires a significant time and resource commitment from healthcare professionals, which in real-life settings is not always possible. The potential effect of this is that many subjects suffering from nocturia might go undiagnosed.

An existing wearable digital communication channel may fill the gap in facilitating appropriate diagnosis of certain conditions (eg, for NP offering a 3-day electronic bladder diary to a digital community through existing software or in the case of sleep disorders, making validated sleep scales available and collecting User-Reported Outcomes).

5 | CONCLUSIONS

Using data from wearables it was possible to establish that there is an association between the typical number of nocturnal voids and objectively measured sleep characteristics. This study showed that nocturia (≥ 2 nocturnal voids) is strongly correlated with the night-time awake duration, SE and FUSP.

Bother and daytime activity impairment are also strongly correlated with the number of nocturnal voids.

This study further adds to the body of evidence on the presence of nocturia in a young general population, clarifying that nocturia is not a condition affecting the elderly people only. Indeed, the results presented here show that the younger population suffering from nocturia have a higher level of associated bother than the elderly people.

Wearables were shown in our study to be applicable for population research, however to date they have not been commonly used for individual diagnosis and monitoring purposes. Leveraging the power of wearables and associated digital communication channels to perform remote diagnosis as well as increase medical literacy and awareness on possible conditions one may suffer from, in a two-way communication model, especially in a young population, could have remarkable beneficial effects.

To what extent such interventions may contribute to quality of care improvement remains an important area for future research.

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DISCLOSURES

Prof. C. Chapple reports: Consultant/Advisor for Bayer Schering Pharma AG, Contura, Ferring, Astellas, Galvani Bioelectronics CLINICAL PRACTICE WILEY

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(GSK), Pierre Fabre, Taris Biomedical, Urovant Sciences. Scientific Study/Trial, Researcher for Ipsen and Astellas. Author for Astellas, Allergan. Meeting Participant, Speaker for Pfizer and Astellas. Patent holder, Symimetics. Research grant received from Astellas. Prof. D. Bliwise is a consultant for Ferring, Merck, Eisai, Jazz. E. Roitmann was previously employed by Withings and worked on this project as an independent researcher under contract with Ferring.

AUTHOR CONTRIBUTIONS

C. Chapple and D. Bliwise, data analysis/interpretation, critical revision of article, approval of article; L. Maislisch, data analysis/interpretation, manuscript writing/editing; E. Roitmann, data extraction, statistics, data analysis/interpretation, manuscript writing/editing; T. Burtea, concept/design, data analysis/interpretation, manuscript writing/editing.

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APPENDIX A

TABLE A1 Prospective 10-item questionnaire

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Sleep questions for prospective Withings survey	Reason to include	Scale
 How satisfied/ dissatisfied are you with your current sleep pattern? 	General assessment of sleep quality	1-5 (Very satisfied to Very dissatisfied)
2. How many times do you wake up during a typical night's sleep? (for whatever reason)	To be able to exclude awakenings as a result of other reasons, like pain or worries	N O 1 time 2 times 3 or more times
3. How often do you usually get up during the night to urinate?	Nocturnal voids	N O 1 time 2 times 3 or more times
4. What is the length of the first period of uninterrupted sleep you usually get at night (DO NOT include time that you spend getting to sleep at night)?	FUSP req. for deep sleep >4 h recommended	Hours and minutes
5. When you awake in the middle of the night, how long does it usually take you to get back to sleep?	Common problem for nocturic patients	Hours and minutes
6. How bothered are you by having to get up to void each night, and thus having a disrupted sleep?	Only bothered patients seek care (about 1/3 of all). This question is used in clinical trials.	Not at all, slightly, moderately, quite a bit, extremely
7. Do you have problems with waking up/getting up too early in the morning?	"No point in going back to sleep since I have to get up in 30 min anyhow" Typical nocturia problem	Never, Sometimes, Often to frequently
8. How many hours do you on average sleep each night?	Need this to compare with non-nocturics	Hours and minutes
9. How much does bothersome night-time urination affect your daytime activities (work, driving, other activities)	Next day consequences, work productivity and risk for accidents	Not at all, slightly, moderately, quite a bit, extremely
10. How refreshed did you feel this morning?	Quality of sleep	Not at all, moderately, quite a bit, a great deal

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APPENDIX B

 TABLE B1
 Number of users by country in the retrospective
 dataset

Inited States50 000France46 187Germany30 518Great Britain26 958Japan10 028Switzerland9027Switzerland722Canada722Spain5306Belgium5304Netherlands3809Sweden3048Netherlands309Sweden2429Austria2429Poland2359Formark1333Poland1799Ireland1282Russia1285Rusnia2429Indand1285States1292States1292States1292States1292States1292States1292States1292States1292States1292States1293<	Country	All
Germany 30 518 Great Britain 26 958 Japan 10 028 China 9027 Switzerland 8376 Finland 7222 Canada 5726 Spain 5306 Belgium 4546 Italy 4408 Netherlands 3809 Sweden 3048 Austria 2429 Norway 2359 Denmark 1833 Poland 1799 Ireland 1529 Russia 1482 Romania 1285 Czech Republic 1279 Hungary 1263 Other ^a 1791	United States	50 000
Great Britain 26 958 Japan 10 028 China 9027 Switzerland 8376 Finland 7222 Canada 5726 Spain 5306 Belgium 4546 Italy 4408 Netherlands 3809 Sweden 3048 Austria 2429 Norway 2359 Poland 1529 Iteland 1529 Russia 1482 Romania 1285 Czech Republic 1279 Hungary 1263 Other ^a 17191	France	46 187
Japan 10 028 China 9027 Switzerland 8376 Finland 7222 Canada 5726 Spain 5306 Belgium 4546 Italy 4408 Netherlands 3809 Sweden 3048 Austraia 2392 Norway 2359 Denmark 1833 Poland 1799 Ireland 1482 Russia 1482 Romania 1285 Czech Republic 1279 Hungary 1263 Other ^a 17191	Germany	30 518
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Switzerland8376Finland7222Canada5726Spain5306Belgium4546Italy4408Netherlands3809Sweden3048Australia2429Norway2359Denmark1833Poland1799Ireland1285Russia1285Czech Republic1279Hungary1263Other ^a 17191	Japan	10 028
Finland 7222 Canada 5726 Spain 5306 Belgium 4546 Italy 4408 Netherlands 3809 Sweden 3048 Austria 2429 Australia 2392 Denmark 1833 Poland 1799 Ireland 1529 Russia 1482 Romania 1285 Czech Republic 1279 Hungary 1263	China	9027
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Belgium4546Italy4408Netherlands3809Sweden3048Austraia2429Australia2392Norway2359Denmark1833Poland1799Ireland1529Russia1482Romania1285Czech Republic1279Hungary1263Other ^a 17191	Canada	5726
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Norway2359Denmark1833Poland1799Ireland1529Russia1482Romania1285Czech Republic1279Hungary1263Other ^a 17191	Austria	2429
Denmark1833Poland1799Ireland1529Russia1482Romania1285Czech Republic1279Hungary1263Other ^a 17191	Australia	2392
Poland1799Ireland1529Russia1482Romania1285Czech Republic1279Hungary1263Other ^a 17191	Norway	2359
IrelandIf 729Ireland1529Russia1482Romania1285Czech Republic1279Hungary1263Other ^a 17 191	Denmark	1833
Russia1482Romania1285Czech Republic1279Hungary1263Other ^a 17191	Poland	1799
Romania1285Czech Republic1279Hungary1263Other ^a 17 191	Ireland	1529
Czech Republic1279Hungary1263Other ^a 17 191	Russia	1482
Hungary1263Other ^a 17 191	Romania	1285
Other ^a 17 191	Czech Republic	1279
	Hungary	1263
Total 250 000	Other ^a	17 191
	Total	250 000

^aIncludes countries with <1000 users.

APPENDIX C

 TABLE C1
 Distribution by country of users who participated in the prospective survey

Country	Number of respondents	Proportion of respondents
France	2107	33.8%
United States	965	15.5%
Germany	962	15.4%
Great Britain	835	13.4%
Japan	415	6.7%
Switzerland	257	4.1%
Spain	180	2.9%
Italy	170	2.7%
Canada	141	2.3%
Australia	100	1.6%
Sweden	89	1.4%
Austria	9	0.1%
Total	6230	100%

APPENDIX E

TABLE E1 Association between night-time bother (Question 6) and age for respondents reporting 2 or more voids per night (Question 3) (n = 885)

Bother	18-44 y	45-64 y	65-90 y
Not at all or slightly	18.24%	22.95%	29.10%
Moderately	32.70%	33.49%	37.79%
Quite a bit or extremely	49.06%	43.56%	33.11%

Note: χ^2 = 14.49, *P*-value < .006, *df* = 4.

TABLE E2Association between daytime bother (Question9) and age for respondents reporting 2 or more voids per night(Question 3) (n = 885)

Bother	18-44 y	45-64 y	65-90 y
Not at all or slightly	52.83%	60.42%	71.91%
Moderately	30.19%	24.12%	21.07%
Quite a bit or extremely	16.98%	15.46%	7.02%

APPENDIX D

TABLE D1Associations between number of nocturnal voids(Question 3) and night-time bother (Question 6)

Bother	0-1 void	2 voids	3 or more voids
Not at all or slightly	53.79%	26.77%	13.97%
Moderately	23.01%	35.84%	30.73%
Quite a bit or extremely	23.20%	37.39%	55.31%

Note: χ^2 = 294.72, P-value < .0001, df = 4.

TABLE D2Associations between number of nocturnal voids(Question 3) and daytime bother (Question 9)

Bother	0-1 void	2 voids	3 or more voids
Not at all or slightly	87.50%	65.58%	52.51%
Moderately	9.15%	23.37%	27.37%
Quite a bit or extremely	3.35%	11.05%	20.11%

Note: χ^2 = 383.15, *P*-value < .0001, *df* = 4.

Note: χ^2 = 22.64, *P*-value < .001, *df* = 4.